JAN - 9 2001

K001802

Pre-market Notification (510k) Summary Information

510k number/Name: K001802/Venodyne DVT Advantage Model 610

Submitters Name: Microtek Medical, Inc.

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Date summary was prepared: June 12, 2000

510K Summary Information

Substantial Equivalence Summary for the
Venodyne DVT Advantage Model 610 Compression System

In accordance with CFR Part 870.5800 this summary is submitted by:

NAME OF THE DEVICE:

Classification Name:	Compressible Limb Sleeve
Product Code:	JOW
Common or Usual Name:	Compressible Limb Sleeve Device
Proprietary Name:	Venodyne DVT Advantage Model 610 Compression System

STATEMENT OF SUBSTANTIAL EQUIVALENCE:

The Venodyne DVT Advantage Model 610 Compression System is Substantially equivalent to the Venodyne Model 510 (510(k) Number: K930526) in that the basis of operation of both devices is the inflation of single chamber leg garments which are placed on a patient's lower limbs. Inflation of the sleeve is accomplished using air, and an inflation/deflation cycle of a predetermined interval. Both systems are electrically powered and connect to the inflatable garments via air tubing.

The Venodyne DVT Advantage Model 610 Compression System is substantially equivalent in function, operating parameters, and indications of use to the commercially available Venodyne Model 510 (510(k) Number: K930526). The only changes made were to the pneumatic control circuitry. This is now a microprocessor-controlled system. This allows for more flexibility in user-error detection and system status reporting to the end-user. Inflation/deflation timing cycles and preset pressures remain unchanged from the predicate device.

DESCRIPTION OF THE DEVICE

The Venodyne DVT Advantage Model 610 Compression System is a microprocessor controlled pneumatic pump that inflates and deflates a set of single chamber leg garments, which are placed on a patient's lower limbs. During the inflation cycle, the inflatable garments compress the limb and the veins contained within to a preset pressure. This assists in propelling the blood from the lower limbs toward the heart. During the deflation cycle, the veins are allowed to refill with blood. The cycle is repeated intermittently.

INDICATIONS FOR USE

The Venodyne DVT Advantage Model 610 Compression System is designed to compress the lower limbs aiding the blood flow back toward the heart to help prevent DVT (Deep Vein Thrombosis) in patients at risk.

TECHNOLOGICAL CHARACTERISTICS

The Venodyne DVT Advantage Model 610 Compression System has the same performance characteristics as the predicate device. The system uses the same air tubing, limb garments and air compressor as the predicate unit. The inflation/deflation and preset pressure parameters remain exactly the same.

The pneumatic control circuitry is now a microprocessor-controlled system. This allows for more flexibility in user-error detection and system status reporting to the end-user. Safety redundancy is built into the system in the form of both software and hardware components. The system will be housed in a molded plastic case and as a result is smaller as well as lighter than the predicate system. Power is supplied via 110 VAC line current.

PERFORMANCE DATA

The Venodyne DVT Advantage Model 610 Compression System performance characteristics are based on the Venodyne Model 510 (510(k) Number: K930526). Both systems have the same inflation/deflation cycles and preset pressures. Both systems utilize the same air tubing and lower limb garments.

Non-clinical validation of the Venodyne DVT Advantage Model 610 Compression System showed that the inflation cycle time for the leg garments to be 12 seconds (same as predicate device), deflation cycle time to be 48 seconds (same as predicate device) and the target pressure to be 45 mmHg (same as predicate device).

EQUIVALENCY CONCLUSION

Results of the non-clinical bench testing of the Venodyne DVT Advantage Model 610 Compression System indicate substantial equivalence to the predicate device. Both devices utilize the same timing parameters, preset pressure parameters, air tubing and limb garments. Both devices supply intermittent compression to the lower limbs to help prevent DVT (Deep Vein Thrombosis) in patients at risk.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 9 2001

Thomas B. Bonner, Jr.
Vice President
Regulatory Affairs/Quality Assurance
Microtek Medical, Inc.
512 Lehmberg Road
Columbus, MS 39702

Re: K001802
Trade Name: Venodyne DVT Advantage Model 610
Regulatory Class: II
Product Code: JOW
Dated: October 9, 2000
Received: October 11, 2000

Dear Mr. Bonner:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), or for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k)
Number: K001802

Device Name	Venodyne DVT Advantage Model 610 (compression system)
Indications for Use	The Venodyne DVT Advantage model 610 is designed to compress the lower limbs aiding the blood flow back toward the heart to prevent DVT (Deep Vein Thrombosis) in patients at risk.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
And Neurological Devices
510(k) Number K001802

Prescription Use X or Over-The-Counter Use _____
(per 21CFR 801.109)

1/8/1

of Cardiovascular & Respiratory Devices
Number # K001802